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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Todd J. Mortier et al.	)	Group Art Unit: 3738
	)	
Application No.: 09/981,790	)	Examiner: D. Willse
	)	
Filed: October 19, 2001	)	
	)	
For: VALVE TO MYOCARDIUM TENSION MEMBERS DEVICE AND METHOD	)	Confirmation No.: 6743

Attention: Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER 37 C.F.R. § 41.41

Pursuant to 37 C.F.R. § 41.41, Appellants submit this Reply Brief in response to the Examiner's Answer mailed on April 5, 2006.

In the Examiner's Answer mailed on April 5, 2006, the Examiner maintains the rejection of claims 64, 66, 67, and 83 under 35 U.S.C. § 102(b) as allegedly being anticipated by Alferness (U.S. Patent No. 5,702,343). Despite the Examiner's application of the Alferness reference in at least three prior Office Actions, the Examiner's "Grounds of Rejection" now cites numerous passages in Alferness for the first time. The newly-cited passages, and the contentions they allegedly support, however, still do not teach a critical limitation of independent claim 83, that the device alters a geometry of heart structure "throughout the cardiac cycle." Instead, the Alferness device is expressly disclosed as acting only during diastole, a *portion* of the cardiac cycle.

In addition, in an attempt to read the claim language so broadly as to sweep in the Alferness disclosure, the Examiner, despite previously making and withdrawing a similar assertion, asserts that the claim term "throughout the cardiac cycle" is not supported by the specification. For that same purpose, the Examiner for the first time also asserts that the claim term "geometry" is not defined in the specification. As will be shown, the originally-filed disclosure expressly supports, and provides examples of, these claim terms.

I. Alferness does not disclose a device that alters a geometry of heart structure throughout the cardiac cycle

In Section (9) of the Answer, the Examiner first contends that placement of a cardiac reinforcement device (CRD) shown in, for example, Figures 3-5 of Alferness under the parietal pericardium results in the altering of heart wall configuration or

geometry. Specifically, the Examiner argues that "significant portions of the heart wall are forced inwardly away from the parietal pericardium by the reaction forces of the constraining CRD jacket materials and structure." The Examiner for the first time cites column 3, lines 14-16; column 4, lines 1-8; and column 7, lines 4-11 of Alferness as allegedly supporting this contention.

The Examiner's contention and citations miss the point. Claim 83 requires altering a geometry of heart structure "throughout a cardiac cycle," which includes diastole *and systole*. The contention that heart wall portions are forced inward due to reaction forces of the Alferness CRD, which Appellants do not necessarily concede, does not even address whether the CRD alters heart structure geometry *throughout the cardiac cycle*. It is entirely possible, and indeed explicitly disclosed, that the CRD provides constraining forces only during diastolic filling. For example, Alferness distinguishes previously known devices by stating that "[i]n contrast to known ventricular assist devices which provide cardiac assistance during systole, a CRD according to the present disclosure provides cardiac reinforcement during diastole." (Column 3, lines 1-5.) Alferness further explains that the CRD does not "impair[] systolic function," but instead only "constrain[s] cardiac expansion, during diastolic filling of the heart." (Column 3, lines 11-14.)

The passages cited by the Examiner also do not teach the claim requirement that heart structure geometry be altered throughout a cardiac cycle. For example, column 3, lines 14-16, states that "[t]he biomedical material should, however, constrain cardiac expansion, *during diastolic filling of the heart*, to a predetermined size." (Emphasis added.) This teaching merely specifies that the CRD material should be capable of

limiting outward expansion of the heart during diastolic filling. It includes no teaching of the CRD altering geometry during systole.

Column 4, lines 1-8, of Alferness, also cited by the Examiner, states:

> A CRD applied to the epicardium is fitted to a "predetermined size" for limitation of cardiac expansion. According to a jacket embodiment, "predetermined size" refers to the predetermined expansion limit of the jacket which circumferentially constrains cardiac expansion *during diastolic filling of the heart*. In practice, for example, a physician could measure cardiac output and adjust the jacket size to an optimal size for the desired effect.

(Emphasis added.) This disclosure once again relates only to a CRD that is sized to limit cardiac expansion during diastole. The CRD applies pressure to the exterior of a heart wall only when the heart begins to exceed the predetermined size of the CRD. The disclosure includes no teaching of the CRD altering geometry during systole.

Column 7, lines 4-11, of Alferness, also newly cited by the Examiner, states:

> In a preferred embodiment, if one or more of the lateral attachment cords 48 is made of an elastic material, such as silicone rubber, surface pressure exerted on the epicardial surface of the heart varies as a function of the amount of dilation. This variable pressure has the effect of reducing cardiac dilation to a certain point and then stopping because the surface pressure drops to a negligible amount.

This disclosure relates to the CRD jacket 40 shown in, for example, Figure 5 of Alferness. Specifically, this teaching addresses the use of elastic attachment cords 48 to secure together opposing lateral edges 46, 47 of CRD jacket 40. Cords 48 result in the CRD applying a surface pressure to the heart wall that is dependent on the size of the heart. The CRD exerts more pressure on a heart that is dilated to a larger size, but exerts only negligible pressure on a much smaller heart. Again, however, although this passage discusses variable pressure exerted by the CRD on different sized hearts, the passage includes no teaching of the CRD altering geometry during systole.

Also in Section (9) of the Answer, the Examiner next alleges that "heart structure is further altered after the device has been adjusted for size reduction." The Examiner for the first time cites column 2, lines 8-18, and column 4, line 43 to column 5, line 16 as allegedly supporting this contention. Like the contention just discussed, altering heart structure after the CRD size has been reduced does not address whether the CRD alters heart structure geometry *throughout the cardiac cycle*.

The passages cited by the Examiner likewise do not support that claim requirement. These passages discuss two mechanisms for adjusting the size of the CRD. The first mechanism includes a slot having opposing edges that may be moved closer together to reduce the slot size and thereby the jacket size. The second mechanism is an inflatable member placed between the jacket and the heart. Jacket size is reduced by inflation of the member. Those passages of Alferness specifically disclose that jacket size is reduced "as therapeutic reduction of cardiac expansion occurs" (column 4, lines 47-51), and, significantly, that "[t]he inflatable member is *not* rhythmically inflated and deflated to provide assistance to cardiac contraction *during systole*" (column 5, lines 14-16; emphasis added). Thus, these passages specifically teach against using the size-reduction mechanisms during systole.

Accordingly, none of the Alferness passages cited by the Examiner teach that the CRD alters heart structure geometry *throughout the cardiac cycle*, as required by the claimed invention. Instead, Alferness explicitly teaches that the CRD jacket only limits the outward expansion of the heart during diastolic filling.

II. Alferness's disclosure relating to the heart's natural reduction in size is not a teaching of altering heart structure geometry during systole

Recognizing that the above-mentioned cited passages do not teach altering heart structure during systole, the Examiner next argues that "[t]he gradual reduction in heart size (column 4, lines 9-11), along with the thickness and lower compliance of the CRD biomedical material (column 3, lines 22-32), clearly alters heart wall geometry during systole *as well*." (Emphasis added.) The Examiner appears to allege that disclosure relating to the heart shrinking in size over time, in combination with a CRD of particular compliance, teaches a CRD that alters heart wall geometry throughout the cardiac cycle.

The cited passages, however, once again discuss the CRD acting only during diastole and contain no disclosure of the CRD acting during systole. For example, column 3, lines 22-32, states that "some limited expansion of the elastic biomedical material can occur during cardiac filling" and a "substantially non-elastic" material is a "material which constrains cardiac expansion during diastole."

Column 4, lines 9-11, also cited by the Examiner, simply states that the CRD size can be reduced as cardiac size is reduced. Alferness merely teaches that certain embodiments of the disclosed CRD jacket may be adjusted to compensate for any therapeutic reduction in cardiac expansion the heart may experience. See column 4, lines 47-51; and column 5, lines 5-8 and 41-44. Alferness suggests that dilated hearts exposed to long term constraint by, for example, the disclosed CRD, may over time experience a natural reduction in size. See, for example, column 4, lines 9-11 and 48-51. However, such reduction, if any, stems from a fortuitous, natural response of the

heart, not from the Alferness device acting to alter heart structure geometry during systole.

Rather, as discussed above, the CRD acts upon the heart to only limit cardiac expansion beyond a predetermined size. Indeed, Alferness explicitly distinguishes the disclosed devices from previously known devices by stating that "[i]n contrast to known ventricular assist devices which provide cardiac assistance during systole, a CRD according to the present disclosure provides cardiac reinforcement during diastole." (Column 3, lines 1-5.) Alferness further explains that the CRD does not "impair[] systolic function," but instead only "constrain[s] cardiac expansion, during diastolic filling of the heart." (Column 3, lines 11-14.)

In contrast, the claimed device directly acts upon the heart during both systole and diastole by constantly applying a force to the heart wall, to alter a geometry of heart structure. Since the devices disclosed by Alferness do not act upon the heart during systole, they do not alter heart geometry throughout the cardiac cycle, as required by independent claim 83.

III. Alferness does not disclose devices that draw together leaflets of a valve

Next, the Examiner alleges that because Alferness discloses a device than can reduce the problems associated with cardiac dilation, including valve leakage due to enlargement of the valvular annulus, Alferness teaches a device that "draws together leaflets of the in situ valve to promote closure of the in situ valve," as required by independent claim 83. The Examiner further alleges that the disclosed Alferness "CRD

jacket alters heart structure which in turn reduces the size of the annulus (and hence draws together the leaflets)." See page 3 of the Examiner's Answer.

As discussed on pages 15-18 of Appellants' Brief filed on January 23, 2006, Alferness does not teach or otherwise suggest a device that acts on the valve or draws together leaflets to close the valve. At most, Alferness may be interpreted to teach that use of the disclosed CRD for constraining cardiac expansion during diastole and preventing cardiac dilation may reduce the naturally occurring consequence of valvular leakage. This, however, is not a teaching of a device that explicitly or inherently "draws together leaflets of the in situ valve to promote closure of the in situ valve."

Moreover, for the purposes of argument, even assuming that the Alferness CRD alters heart structure in the manner alleged by the Examiner, which Appellants do not concede, Alferness includes no disclosure of such alteration having any effect whatsoever on the size of a heart valve annulus. Indeed, Alferness includes no disclosure that suggests that any fortuitous reduction in valvular leakage *necessarily* results from a reduction in the size of the valvular annulus. The possibility exists for valvular leakage to reduce as a result of the heart simply being constrained against undesirable expansion beyond a predetermined limit.

Therefore, contrary to the Examiner's allegations, Alferness does not disclose or otherwise suggest a device that acts on the valve or draws together leaflets of the valve to promote closure of the valve.

IV. The specification supports the claim language "throughout the cardiac cycle"

Turning to Section (10) of the Answer, the Examiner alleges that "[t]he language 'throughout the cardiac cycle' (claim 83, lines 2-3) is nowhere to be found in the original disclosure, particularly with regard to passively altering geometry of 'other' heart structure (claim 83, lines 3-5)." The Examiner makes this allegation in an attempt to interpret that language so broadly so as to sweep in the Alferness disclosure.

Notably, the Examiner previously raised a similar allegation in a 35 U.S.C. § 112, first paragraph, rejection made in the Office Action of April 1, 2004. Specifically, the Examiner contended that "[t]he original disclosure fails to disclose . . . positioning a passive device such that, at least **during systole**, a portion of the device contacts and passively alters a geometry of heart structure . . . ." (Emphasis in original.) See page 2 of the April 1, 2004, Office Action. However, in response to Appellants' remarks in the Amendment filed on May 10, 2004, the Examiner did not maintain the Section 112 rejection in the subsequent communication dated October 5, 2005.

The originally-filed specification supports the language "throughout the cardiac cycle," particularly with respect to altering geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus. As discussed on page 7 of the application, and with reference to Figure 5, embodiments of the claimed device are intended to treat mitral valve insufficiency, a condition in which the leaflets of a mitral valve do not close properly during the systolic phase of the cardiac cycle, in order to prevent blood flow leaking from the left ventricle back into the left atrium. That is to say, "an opening 26 is left between leaflets 16 throughout the cardiac cycle." See page 7, lines 8-9. Mitral valve insufficiency may occur in a dilated heart because chamber

dilation and associated high wall stresses increase the diameter of the mitral valve annulus.

To help eliminate the opening 26, embodiments of the claimed device, such as the embodiments depicted in Figures 9-10, among other things, alter the geometry of the left ventricle by placing a transverse tension member 225, 325 to draw at least two walls of the left ventricle toward each other. This reduces wall tension, improves chamber performance, and promotes closure of the valve leaflets. Tension members 225, 325 are implanted on the heart so that they constantly (i.e., throughout the cardiac cycle) draw opposing heart walls together. In disclosing the manner in which the tension member 225 is used to alter left ventricle geometry, the specification incorporates by reference the disclosure of U.S. Patent Application No. 08/933,456, now U.S. Patent No. 5,961,440. (See page 8, line 25 - page 9, line 4 of the specification.) That incorporated disclosure teaches that such tension members act on the heart to reduce wall tension *during both diastole and systole*. See column 2, lines 54-55 of U.S. Patent No. 5,961,440; and Figures 36-40. To reduce wall tension during both diastole and systole, the tension members must necessarily act to alter heart structure geometry during both diastole and systole. Thus, the present specification sufficiently describes that tension members 225, 325 alter heart geometry by drawing opposing heart walls toward each other during both diastole and systole (i.e., throughout the cardiac cycle).

Accordingly, the Examiner's further assertion on page 4 of the Answer that Appellants have not shown that the present invention alters geometry of heart structure other than leaflets, chordae, papillary muscles, and an annulus during systole (see Answer at page 4) is simply not correct. Rather than Appellants' disclosed method

simply *inherently* meeting the limitations of independent claim 83 as alleged by the Examiner, Appellants' specification *expressly* discloses those limitations. The Alferness device, on the other hand, as discussed above and in Appellants' previously-filed Appeal Brief, neither explicitly nor inherently meets the limitations of claim 83.

V. The specification discloses examples of "geometry"

Next, the Examiner for the first time alleges that "the term 'geometry' has *not* been defined by the Appellant in a manner prescribed by MPEP § 2111.01." (Emphasis in original.) The Examiner also makes this allegation in an apparent attempt to interpret that term so broadly so as to encompass the Alferness disclosure.

M.P.E.P. § 2111.01, however, does not mandate that the specification provide a definition of a claim term. Instead, that Section states, among other things, that the words of a claim must be given their plain meaning unless applicant has provided a clear definition in the specification.

Nonetheless, the present specification discloses exemplary embodiments of "geometry," as used in connection with heart structure. Section 2111.01 cautions, however, that "especially in nonchemical cases, the words in a claim are generally not limited in their meaning by what is shown or disclosed in the specification." So, here, the term "geometry" is not necessarily limited in its meaning to the following exemplary embodiments.

As a first example, the term "geometry," when used in connection with altering of the left ventricle, at least includes the transverse radius and vertical dimension of the left ventricle. See page 6, lines 18-25 of the originally-filed specification. As another

example, with regard to tension member 225, incorporated U.S. Patent No. 5,961,440 states that such a tension member draws at least two walls of the heart chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane. See column 2, lines 56-59; and column 5, lines 53-61, in U.S. Patent No. 5,961,440. In addition, Figures 36-40 and the corresponding written description of those Figures in the incorporated '440 patent disclose an exemplary left ventricle having its radius and cross-section altered. Specifically, Figures 37-40 show a heart chamber 48 altered such that a figure eight cross-section has been formed along its length. Based on at least these examples, the term "geometry," as used in independent claim 83, is sufficiently defined in the present application.

VI. Conclusion

For at least the above reasons, Alferness fails to disclose or otherwise suggest, either explicitly or otherwise, a method for treating an in situ mitral valve, as recited in independent claim 83. Accordingly, Appellants respectfully request that the Section 102 rejection based on Alferness be withdrawn and claim 83 and its dependents allowed.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Reply Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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By: 

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